

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. In the claims

Claims 6, 25 and 40 are amended to recite that the strip is incapable of securely fixing and rigidly immobilizing the blank on the anatomy as a sole securing means. Support for this amendment is found in paragraphs [00013] and [00014] of the specification, as originally filed.

Claim 6 is amended to specify that the primary tacking arrangement is configured for adjustably holding the blank in place on an injured part of a patient's anatomy. Claim 6 is also amended to recite that the blank is still adjustable with respect to the anatomy when the hook type patch on the first end portion is received by the hook receivable material on the blank and the hook type patch on the second end portion is received by at least one of the hook receivable material on the blank and the non-woven material. Claims 25 and 40 are amended to include similar features. Support for these amendments is found in paragraphs [0003], [0004] and [00035] of the specification, as originally filed.

Claims 6, 25 and 40 are also amended to provide proper antecedent basis to the terms "injured part" and "patient," and to delete the language "of insufficient strength to rigidly immobilize the splint for long-term use."

Claims 41, 42 and 44 are amended to improve the clarity of the claim language.

It is clear that there is support in the specification for the amendatory language; thus, no new matter is added by these amendments.

Entry of the Amendment to the claims is respectfully requested in the next Office action.

2. Rejection of claims 6, 25, 40-42 and 44 under 35 U.S.C. § 112

Reconsideration and withdrawal of this rejection is respectfully requested in view of the amendments to the claims, as described above. Particularly, the claims have been amended to provide the terms “injured part” and “patient” with proper antecedent basis.

Additionally, the language “of insufficient strength to rigidly immobilize the splint for long-term use” has been deleted.

However, the term “rigidly immobilize” has been retained in the claims. It is submitted that this term is clearly defined in the specification (paragraphs [00013] and [00014]). Specifically, the specification describes that the primary tacking arrangements are temporary locating arrangements that permit easy adjustment of the splint position and further that the tacking arrangements are of insufficient strength to rigidly immobilize the splint for long term use by the patient.

In paragraph [0014], lines 1-3, the specification explicitly defines the term “tacking” as primary holding arrangements that are of insufficient strength to fully secure the splint. It is further described that subsequent secondary securing arrangements, which are of sufficient strength to properly immobilize the splint to the patient, are applied in addition to the primary tacking arrangements in order to fully secure the splint to the patient.

In view of the descriptions in the specification of the primary tacking arrangement, which is of insufficient strength to rigidly immobilize the splint for long term use, in contrast with the descriptions of the secondary securing arrangements, which are strong enough to properly immobilize the splint, it is submitted that one skilled in the art would understand precisely what is meant by the terms “primary tacking arrangements” and “rigidly immobilize.”

It is additionally submitted that the term “rigidly immobilize” has been used in the application in a manner consistent with the ordinary meanings of the words “rigidly” and “immobilize.”

It is submitted that all of the features of the claims are now clearly defined and provided with proper antecedent basis. Accordingly, withdrawal of this rejection is kindly requested.

3. Rejection of claims 6, 9, 10, 14, 18, 20-22 and 25-28 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (*Darcey*) in view of U.S. patent application publication 2002/0193718 (*Henderson*), and further in view of U.S. patent application publication 2002/0022108 (*Krantz*)

Reconsideration of this rejection is respectfully requested in view of the amendments to independent claims 6 and 25, from which the remaining claims in the rejection depend, and the following remarks which demonstrate that the proposed combination of *Darcey*, *Henderson* and *Krantz* fails to render the pending claims *prima facie* obvious.

Independent claims 6 and 25 require a splint comprising a primary tacking arrangement configured for adjustably holding a blank in place on an injured part of a patient's anatomy such that the blank is still adjustable with respect to the anatomy when a hook type patch on a first end portion of the primary tacking arrangement is received by hook receivable material on the blank and a hook type patch on a second end portion of the primary tacking arrangement is received by at least one of the hook receivable material on the blank and hook receivable material of the primary tacking arrangement.

The claims further require that the primary tacking arrangement is incapable of securely fixing and rigidly immobilizing the blank on the anatomy as a sole securing means.

The primary tacking arrangement is a temporary strap that holds the orthopedic blank so as to enable single-person application of a secondary securing means which immobilizes the blank to the injured anatomy. The primary tacking arrangement is extremely lightweight and low profile. Also, when stretched, the

primary tacking arrangement gradually tears over relatively small loads before completely separating.

The unique combination of strength, stretch and tear properties of the primary tacking arrangement allow it to be strong enough to adjustably hold the orthopedic blank such that a single person can apply the secondary immobilizing means, yet delicate enough such that the primary tacking arrangement does not create pressure points or restrict circulation.

It is submitted that the proposed combination of *Darcey*, *Henderson* and *Krantz* fails to render obvious independent claims 6 and 25, because the proposed combination does not teach or suggest every feature of the pending claims. It is further submitted that combining the references as proposed would render the splint assembly in *Darcey* inoperative for its intended purpose.

MPEP 2143.01 (V) states that if a “proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” The *2010 KSR Guidelines Update* states, in example 4.6, that the “predictable result” discussed in *KSR* refers not only to the expectation that the prior art elements are capable of being physically combined, but also the expectation that the combination would have worked for its intended purpose.

It is submitted that *Darcey* teaches away from the proposed combination such that the skilled artisan would have actually been deterred from combining the references as proposed; thus, it would not have been obvious to combine the references as proposed in the rejection.

The rejection relies on the splints 14 and the straps 26 in *Darcey* as respective teachings of the orthopedic blank and the primary taking arrangement of claims 6 and 25.

Darcey discloses that the straps 26 are used to secure the splints 14 to the hand and wrist of a patient (col. 7, lines 5-10; Fig. 8-10). The straps 26 are formed of a

woven or knitted material 27 having a loose, fibrous covering 28 on its surface (col. 7, lines 7-10). The straps 26 have a D-ring 30 at one end and a patch of hook material 32 at the other end so that the straps 26 can be sufficiently tightened to securely fix the splints 14 on the patient's hand and wrist (col. 7, lines 9-11 and 27-29).

The splints 14 and straps 26 in *Darcey* are overwrapped with an elastic bandage 34 at least until the splints are completely hardened into proper conformation on the patient's hand and wrist (col. 7, lines 30-35). Once the splints are hardened, the elastic bandage can be removed and the splints can be worn with only the straps 26 securing the splints to the patient (col. 7, lines 35-37).

Since the splints can be secured on the patient by the straps 26 alone, the straps 26 of *Darcey* are clearly capable of securely fixing the splints to the patient as a sole securing means. Therefore, it cannot be said that the straps 26 are "incapable of securely fixing and rigidly immobilizing the blank on the anatomy as a sole securing means."

Further, since the straps 26 utilize a D-ring 30 to aid in tightening the straps for securely immobilizing the splints to the patient, as discussed above, the straps clearly do not hold the splints in place in a manner that is adjustable so as to allow adjustment of the splints with respect to the patient, as is required by amended claims 6 and 25.

Turning to *Henderson*, this document discloses a hardenable orthopedic support 10. Paragraph [0028] of *Henderson* indicates that the orthopedic support 10 can be held in place by a temporary aide. *Henderson*, however, provides no discussion of how of the temporary aide is applied, or whether the temporary aide is merely removed once the blank is cured or rather overwrapped with an additional securing means. *Henderson* also provides no indication that the temporary aide is applied in a manner that allows adjustment of the blank.

As such, *Henderson* does not make up for the shortcomings of *Darcey*. It is further submitted that since *Darcey* teaches away from the claimed invention, the

skilled artisan would not have been inclined to modify the references as suggested. That is, the skilled artisan would have actually been deterred from combining the references as proposed, since *Darcey* teaches that the straps are indeed capable of alone securely fixing the splints to the patient.

Accordingly, it is submitted that modifying the straps 26 in *Darcey* to be incapable of securely fixing and rigidly immobilizing the splint on the anatomy as a sole securing means would have rendered the splint assembly 10 in *Darcey* inoperative for its intended purpose of being effectively worn by the patient with only the straps 26 securing the splints 14 to the patient.

Turning now to the *Krantz* publication, the rejection relies on this document for the teaching of a strip of hook and loop tape comprising a non-woven material and having opposed end portions with hook type patches. The hook and loop tape (100) of *Krantz* comprises an elastic layer 110 laminated to a fastening layer 120. The fastening layer 120 has a base layer 122 and linear bands 125 of rows of hook elements 124a, 124b, the stems of which are integrally molded with the base layer 122 (paragraph [0097]).

Between the bands of hook elements 124a, 124b are discontinuities in the base layer that provide parting regions 126 (Fig. 5). When tension is applied along a stretching direction 130, the elastic layer 110 is elongated and any material of the fastening layer existing at the parting regions 126 is ruptured. When the tension is relaxed, the fastener 100 returns to its original dimensions while any material of the fastening layer 120 in the parting regions 126 is irreversibly ruptured (paragraph [0107]).

If a flexible, nonelastic carrier sheet is employed, the sheet is capable of flexing at the cut lines or in the regions between the hook bands to achieve a product of enhanced flexibility (paragraph [0102]).

Essentially, *Krantz* provides a fastener having an elastic backing layer and a nonelastic layer laminated thereto that includes hook elements such that when

stretched, the nonelastic layer ruptures, thereby causing the hook elements to be stretched along with the elastic layer. When the tension is released, however, the elastic layer returns to its original dimensions.

It is noted that such an arrangement is in contrast to the device of the instant invention which tears when stretched under relatively small loads and does not return to its original shape so as not to create pressure points or restrict circulation.

It is further noted that *Krantz* provides no indication that the fastener can be applied in a manner that would allow adjustment of a device being supported by the fastener. It would appear that the rebounding effect of the elastic layer 110 would cause the fastener to tightly compress around the device being supported. Such features also suggest that the fastener would indeed be capable of securely fixing and rigidly immobilizing an orthopedic blank on a patient's anatomy as a sole securing means. At a minimum, it would be improper to assert that *Krantz* discloses or suggests a fastener that is incapable of securely fixing and rigidly immobilizing the blank on the anatomy as a sole securing means.

As such, it is submitted that the teachings of *Darcey*, *Henderson* and *Krantz*, as a whole, do not teach or suggest a primary tacking arrangement configured for adjustably holding a blank in place on an injured part of a patient's anatomy such that the blank is still adjustable with respect to the anatomy when a hook type patch on a first end portion of the primary tacking arrangement is received by hook receivable material on the blank and a hook type patch on a second end portion of the primary tacking arrangement is received by at least one of the hook receivable material on the blank and hook receivable material of the primary tacking arrangement, as recited in amended claims 6 and 25.

Likewise, the proposed combination of *Darcey*, *Henderson* and *Krantz* also does not teach or suggest a primary tacking arrangement that is incapable of securely fixing and rigidly immobilizing the blank on the anatomy as a sole securing means, as recited in amended claims 6 and 25.

In view of these observations, it is respectfully submitted that the proposed combination of *Darcey*, *Henderson* and *Krantz* fails to render the pending claims of this rejection *prima facie* obvious. Accordingly, withdrawal of this rejection is kindly requested.

Claims 9, 10, 14, 18, 20-22 and 26-28 are also considered to be patentable as containing all of the elements of claims 6 and 25, as well as for their respective individually recited features.

4. Rejection of claims 15, 29 and 40-47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (*Darcey*) in view of U.S. patent application publication 2002/0193718 (*Henderson*) and U.S. patent application publication 2002/0022108 (*Krantz*), and further in view of U.S. patent 6,139,513 (*Grim*)

Reconsideration of this rejection is respectfully requested in view of the amendments to independent claim 40, from which the remaining claims in the rejection depend, and the following remarks which demonstrate that the proposed combination of *Darcey*, *Henderson*, *Krantz* and *Grim* fails to render the pending claims *prima facie* obvious.

It is submitted that independent claim 40 is patentable for the same reasons discussed above with regard to claims 6 and 25. *Grim* is cited merely as a teaching of a blank in roll form. It is submitted that *Grim* does not make up for the shortcomings of *Darcey*, *Henderson* and *Krantz*.

In view of these observations, it is respectfully submitted that the proposed combination of *Darcey*, *Henderson*, *Krantz* and *Grim* fails to render the pending claims of this rejection *prima facie* obvious. Accordingly, withdrawal of this rejection is kindly requested.

Claims 15, 29 and 41-47 are also considered to be patentable as containing all of the elements of claims 6, 25 and 40, as well as for their respective individually recited features.

5.

Rejection of claim 11 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (Darcey) in view of U.S. patent application publication 2002/0193718 (Henderson) and U.S. patent application publication 2002/0022108 (Krantz), and further in view of U.S. patent 6,039,706 (Bolla)

Rejection of claims 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (Darcey) in view of U.S. patent application publication 2002/0193718 (Henderson) and U.S. patent application publication 2002/0022108 (Krantz), and further in view of U.S. patent 5,195,944 (Schlogel)

Rejection of claims 48 and 49 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (Darcey) in view of U.S. patent application publication 2002/0193718 (Henderson) and U.S. patent application publication 2002/0022108 (Krantz), and further in view of U.S. patent 5,755,678 (Parker)

Rejection of claim 50 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent 6,106,492 (Darcey) in view of U.S. patent application publication 2002/0193718 (Henderson), U.S. patent application publication 2002/0022108 (Krantz) and U.S. patent 6,139,513 (Grim), and further in view of U.S. patent 5,755,678 (Parker)

Reconsideration of these rejections is respectfully requested in light of the observations noted above and the amendments to independent claims 6, 25 and 40, from which claims 11, 23, 24 and 48-50 depend.

It is submitted that *Bolla*, *Schlogel*, and *Parker* do not make up for the shortcomings of *Darcey*, *Henderson*, *Krantz* and *Grim* and thus claims 11, 23, 24 and 48-50 are patentable at least in view of their dependency from claims 6, 25 and 40. Accordingly, withdrawal of these rejections is respectfully requested.

6. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

BACON & THOMAS, PLLC
625 Slaters Lane, Fourth Floor
Alexandria, Virginia 22314-1176
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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Respectfully submitted,



JUSTIN J. CASSELL
Attorney for Applicants
Registration No. 46,205